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09/676,380	09/29/2000	Andre T. Baron	07-277	1919

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EXAMINER	
BORGEEST, CHRISTINA M	
ART UNIT	PAPER NUMBER
1649	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	09/676,380	BARON ET AL.	
	Examiner	Art Unit	
	Christina Borgeest	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 November 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date. _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment After Quayle Action

Withdrawal of Finality

The indicated allowability of claims 18-31 is withdrawn due to reconsideration. Rejections based on the new matter follow.

Objection Maintained

The objection to the amendment filed 29 January 2008 under 35 U.S.C. 132(a) because it introduces new matter into the disclosure as set forth at pages 3-4 of the Office action mailed 14 April 2008 is maintained for reasons of record and the following. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the substitute sequence listing—Appendix A. Applicants state in their remarks filed 14 November 2008 that:

> In response to the Examiner's remaining questions, the errors in the sequence listings of the pending application were discovered when a new attorney began working on the application, supported by the change in power of attorney in the record, and the sequence was subsequently investigated and an amendment filed. No resequencing was performed because there was no sequencing error. The error was only in the sequence listing of the patent application, as indicated by the GenBank report attached to Applicants' previous response dated June 13, 2008. The correct sequences were submitted to GenBank on February 1, 1999, about 7 months prior to the priority date of the current application, thus showing that Applicants were in possession of the sequence at the time of filing.

The Examiner has a remaining concern about the GenBank report attached to Applicants' previous response dated 13 June 2008. The top of the page shows a date of 26 January 2001, which is after the priority date of the instant application. The date of 1 February 1999 appears to be the date of submission to the journal. The submitted date is not the date of public availability, but rather that date is the date the journal article in Genomics 71 (1) 1-20 (2001) was published, which was January 2001. The explanation of how the error was discovered (by a new attorney of record working on the application) is sufficient to support the due diligence in correcting the error, but Applicants' evidence in the form of the GenBank report does not support a submission of the sequence before the priority date.

Applicant is required to correct this issue in the reply to this Office Action.

New Objection/Rejections

Objection to Specification

The amendment filed 2 September 2002 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: There is no explanation regarding the change on p. 1, line 18 to "[the] present invention also provides diagnostic methods for assessing the risk of ovarian cancer…".

In addition, the Examiner was unable to locate where the amendments listed at pages 2-9 of the response of 2 September 2002 are supported in the original

specification. Applicant has not attempted to explain where support can be located. It is noted that Applicant should specifically point out the support for any amendments made to the disclosure. See MPEP § 714.02 and §2163.06. For instance, of particular concern are the following changes:

p. 2, line 4, replacement of "c-erbB1" with "EGFR/ERBB1"

p. 2, line 6, replacement of "1991" with "1990"

p. 2, line 7, replacement of "20" with "90"

p. 2, line 15, addition of unsupported text

p. 2, line 22, addition of unsupported text

p. 2, line 23, replacement of "2.6-2.7" with "1.8-2.8"

p. 2, line 24, addition of unsupported text

p. 2, line 25, addition of unsupported text

p. 3, line 11, replacement of "763" with 753"

p. 4, line 9, replacement of "endothelial" with "epidermal"

p. 6, line 15, addition of unsupported text

p. 6, line 19, addition of unsupported text

p. 7., line 11, addition of unsupported text

p. 7., line 23, addition of unsupported text

p. 7, line 25, addition of unsupported text

p. 8, line 1, addition of unsupported text

p. 8, line 2, replacement of "increasing" with "altering"

p. 8, line 17, addition of unsupported text

p. 9, lines 8, 17, 19 and 20, addition of unsupported text

p. 11, line 8, replacement of "=40" with "=144"

p. 11, line 17, replacement of “endothelial” with “epithelial”

p. 12, line 22, replacement of “that is not anchored to the membrane of a cell,” with “that does not harbor a transmembrane domain”

p. 12, line 24, replacement of “organism” with "cell" and addition of unsupported text

p. 13, line 3, replacement of “EGFR” with “sEGFR”

p. 13, line 6, addition of unsupported text

p. 13, line 21, replacement of "ice" with "mouse"

p. 14, line 21, replacement of “ErbB1” with EGFR/ERBB1”

p. 14, line 23, addition of unsupported text

p. 17, line 2, addition of unsupported text

p. 17, line 19, replacement of “histological” with “stage, grade, histological and molecular”

p. 17, line 24, replacement of “DNA” with “cDNA”

p. 18, line 5, deletion of “inactive”

p. 18, line 6, replacement of “EGFR" with “ErbB family members”

p. 18, line 6, replacement of “EGFR" with “ErbB receptors”

p. 18, line 7, replacement of “EGFR” with “receptor”

p. 18, line 8, replacement of “activity of the EGFR" with "and other signaling activities of ErbB receptor tyrosine kinases"

p. 18, line 16, replacement of "DNA" with "cDNA"

p. 25, line 15, addition of unsupported text

p. 30, line 11, replacement of “EGFR” with "sEGFR”

p. 31, line 1, addition of unsupported text

p. 31, line 12, addition of unsupported text

p. 32, line 22, addition of unsupported text

p. 34, line 5, removal of “below”

p. 34, line 17, replacement of “c-erbB1” with “EGFR/ERBB1”

p. 34, line 22, replacement of “1” with “2”

p. 35, line 1, replacement of “1986 with “2086”

p. 35, line 17, replacement of “represented” with “encoding” and “cDNA” with “sEGFR”

p. 35, line 25, replacement of “EX15F and EX15R” with “pEX15F (SEQ ID NO:9) and pEX15BR (SEQ ID NO:13)”

p. 36, line 2, deletion of "RNA represented by"

p. 36, line 4, addition of unsupported text

p. 36, line 13, deletion of “(p110)(SEQ ID NO: 1)”

p. 36, line 13, deletion of “amino”

p. 36, line 4, deletion of “acids”

p. 36, line 24, replacement of “c-erbb1” with EGFR/ERBB1”

p. 36, line 25, replacement of “transcript” with “EGFR/ERBB1”

p. 37, line 1, replacement of “681” with “705”

p. 37, line 1, deletion of “after cleavage of the signal peptide”

p. 37, line 5, addition of unsupported text

p. 37, line 5, addition of unsupported text

p. 37, line 6, replacement of sErbB1” with “EGFR/ERBB1” and replacement of “encodes” with “synthesizes”

p. 37, line 6, replacement with “glycosylated polypeptide (p110 sErbB1)”

p. 37, line 14, replacement of “gCI” with μCI”

p. 38, line 1, addition of unsupported text

p. 38, line 5, replacement of “mammalian” with “eukaryotic”

p. 38, line 10, replacement of “c-erbB1” with ErbB1”

p. 38, line 26, replacement of “produces” with “encodes”

p. 39, line 9, deletion of "(Figure 7A)".

p. 39, line 18, addition of "may" before "route" and replacement of "and that" with "whereas".

p. 39, line 19, replacement of "will" with "may"

p. 40, lines 4, 5 and 6, deletion of "Cultures of ovarian carcinoma cells exposed to sEGFR preparations have reduced growth rates compared to cells which are not exposed to sEGFR. Thus, sEGFR can inhibit carcinoma cell proliferation."

p. 40, line 24, replacement of "(MAb)" with "(MAbs)".

p. 41, line 4, replacement of "compete" with "complete"

p. 41, line 15, deletion of (MAbs).

p. 41, line 23, replacement of “ErbB 1” with “sErbB 1”

p. 41, line 25, replacement of "ErbB 1" with "sErbB 1"

p. 42, line 5, replacement of "Accession Nos. _____, _____, _____, and" with "HB-12204, HB-12205, HB-12206, and HB-12207"

p. 43, line 8, replacement of "as well as to demonstrate that serum samples of healthy men and women contain a sErbB 1 analog of approximately 110 kD (See Figure 14)" with "and in patients with ovarian cancer"

p. 44, line 19, replacement of "c-erbB 1" with "EGFR/ERBB 1"

p. 44, line 24, replacement of "c-erbB 1" with "EGFR/ERBB 1"

p. 45, line 1, replacement of "c-erbB 1" with "EGFR/ERBB 1"

p. 45, line 6, replacement of "c-erbB 1" with "EGFR/ERBB 1"

p. 45, line 7, replacement of "c-erbB 1" with "EGFR/ERBB 1"

p. 45, line 8, replacement of "c-erbB 1" with "EGFR/ERBB 1"

p. 45, line 10, replacement of "c-erbB 1" with "EGFR/ERBB 1"

p. 45, line 14, replacement of "(648)" with "(G418)"

p. 46, line 20, 10, and p. 47, line 11, replace "FPLCO" with "FPLC"

p. 49, line 1, replacement of "the subdomain" with "subdomain IV"

p. 51, line 17, replacement of "ALISA, believed to be the same 110 kD protein isolated from a human placental cDNA library as described above and is comprised of the 110 kD p110 sErbB 1 SEQ ID NO. 2, and its variants" with "ALISA. Microsequence analysis of partially pure p110 sErbB 1 from human serum using Matrix Assisted Laser Desorption/Ionization-Time of Flight Mass Spectrometry shows that this protein is derived from the 3.0 kb alternative transcript having SEQ ID NO. 2 of the invention

p. 52, line 1, replacement of "appears to be less sensitive and accurate than the" with "differs substantially from the"

p. 53, line 10, replacement of "00" with "60"

p. 53, line 12, replacement of "< or > 00 IU/L, and LH level < or > 00 IU/L "with <30 IU/L (premenopause) or >36 IU/L (postmenopause)"

p. 59, line 3, replacement of "(ú)" with "(ω)".

p. 59, line 6, replacement of "Table 4" with "Table 2"

p. 63, line 18, replacement of "Atairgin" with "TBIG"

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 24 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

There is no support in the specification as originally filed for "saliva" as a patient biological sample. See also the objection to the specification.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 18-32 are rejected under 35 U.S.C. 103(a) as being obvious over Baron et al. ((Journal of Immunol. Methods, 1998: 219: 23-43—on Applicants' 1449 form—on Applicants' 1449 form) in view of Baron et al. Proceding of the American Association of

Cancer Research, Annual Meeting (March, 1999); 40: 43, Abstract #237—on Applicants' 1449 form).

The first factor to consider when deciding if claims are obvious is to determine the scope and contents of the prior art. Baron et al. (1998) teach obtaining serum samples from normal human males and females (page 25, bottom of right column; page 34, left column) in which a sandwich type assay is used to detect levels of serum epidermal growth factor receptor (sERbB1). Specifically, Baron et al. (1998) teach contacting a labeled first antibody that reacts with an epitope of the extracellular ligand binding domain of sERbB1 with said serum sample, and then contacting said serum sample with a second acridinium labeled antibody to detect the co-presence of the first and second labels to determine the concentration of sErbB1 complexed with the antibodies wherein one of the antibodies is mAb R.1 and wherein the other antibody is mAb 528 (see pages 27, left column through 28, whole page; claims 26-31; p. 30, left column; page 34, left column). Baron et al. (1998) teach the combination of mAb R.1 and mAb 528 as recited in claim 18 (see especially, p. 30, left column; meets the limitations of claims 18 and 32):

> In our experience, two well-characterized MAbs, designated R.1…and 528…comprise a useful combination. In its final configuration, an affinity-purified goat anti-mouse IgG_{2b} specific polyclonal antibody is attached first to a…microtiter plate by covalent bonds; this antibody is used to bind MAb R.1, which is of the IgG isotype. MAb R.1 serves to capture analytes that harbor the ECD of ErbB1. Detection and measurement of ErbB1 ECD related analytes is subsequently achieved by binding acridinium-labeled MAb 528, which is of the IgG_{2a} isotype…

The sandwich assay methods taught by Baron et al. (1998) have increased sensitivity (see for example p. 39, left column, 2nd paragraph). In addition, throughout

Baron et al. (1998), it is suggested that various bodily fluids are suitable for use in their methods (see, for example, p. 25, right column, 1st paragraph; p. 29, right column, last paragraph; p. 40, left column, last paragraph). In addition, Baron et al. discuss that sErbB1 has been measured in urine (see for example, p. 25, left column, 1st paragraph), thus the person of ordinary skill in the art (POSITA) would understand that the methods could be applied to bodily fluids such as urine (as recited in claim 24). Although the ALISA method of Baron et al. (1998) is silent with respect to the label of the first antibody or that it is labeled with biotin (claim 27), it is well known in the art that the primary antibody is often labeled with an avidin-biotin complex. The person of ordinary skill in the art, or POSITA, would be well informed of such methods and therefore does not present a true limitation.

The second factor is to ascertain the differences between the prior art and the claims at issue. Baron et al. (1998) do not teach comparing the concentration of sErbB1 measured in step d) of claim 18 with a normal value and correlating a ***decrease*** in the concentration of sErbB1 with the presence of an ovarian carcinoma in the patient. Baron et al. (1999) teach that (sErbB1) levels measured in the serum of patients with stage III or IV epithelial ovarian cancer are lower than the levels in healthy woman of similar ages (see whole abstract—claims 18, steps e and f, 19, 20). In addition, the authors found that sErbB1 changed temporally for some patients who underwent surgery and provided a second serum sample during the course of combination chemotherapy (see whole abstract, claim 21). Finally, the authors found that sERbB1 levels differ between cancer patients and healthy woman and that sErbB1 levels may

provide diagnostic and/or prognostic information (see whole abstract, claims 22 and 23). In short, these teachings specifically meet the limitations of an assay that comprises obtaining a serum sample from a female, comparing the concentration of sERbB1 levels to a normal value (i.e, age matched healthy females) and correlating a decrease in the concentration of sERbB1 levels with the presence of ovarian carcinoma (claims 18, 19, 25). Baron et al. (1999) also teach performing a second assay at a point in time after the initial assay, wherein the patient has undergone treatment (claims 20, 21), and that sERbB1 levels changed temporally for some EOC patients after treatment of the carcinoma with surgery and chemotherapy (claims 22, 23).

This segues into the third factor to be considered in an obviousness rejection, which is to resolve the level of ordinary skill in the pertinent art. Given the discussion in Baron et al. (1998), it is clear that the level of skill in the art of sandwich assays was high, and that the POSITA would know and understand how the methods of Baron et al. (1998) could be used to carry out the assays described in Baron et al. (1998).

The final factor that must be considered is to weigh the objective evidence present in the application indicating obviousness or nonobviousness. In the instant case, Baron et al. (1999) teach the unexpected results that sErbB1 is lower in patients with epithelial ovarian cancer. Furthermore, Baron et al. (1998) teach the same assays and antibodies disclosed in the specification as having greater sensitivity. It would have been obvious to the POSITA at the time the invention was made to conduct the assays described in Baron et al. (1999) using the methods described in Baron et al. (1998) because they taught a superior method of sErbB1 detection. The POSITA would

be motivated to make the modification taught in Baron et al. (1998) because of its report of a higher sensitivity. In addition, the POSITA reasonably would have expected success because the sandwich assay for measuring sErbB1 described by Baron et al. 1998 reported increased sensitivity and the experimental design for carrying out the diagnostic assay recited in claim 18 was previously described by Baron et al. (1999; i.e., comparison of sErbB1 levels in diseased patients and healthy controls with the result that lower levels of sErbB1 are indicative of ovarian carcinoma). Therefore, the claimed invention as a whole was clearly *prima facie* obvious over the prior art.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 18-32 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 22-49 of copending Application No. 12/206,445. Although the conflicting claims are not identical, they are not patentably distinct from each other because in both cases, the claims of the respective applications are drawn to the measurement of soluble EGFR in order to determine whether the patient has ovarian cancer. The instant application contains details such as the steps of the sandwich assay and the antibodies used, however, the claims of the '445 application also recite sandwich-type immunoassays (see, for example, claim 28), which are well known in the art. Thus the addition of details such as type of antibodies used in the instant claims are not sufficient to distinguish them over the claims of the '445 application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Claims 18-32 are rejected. The amendments to the specification (dated 2 September 2002 and 29 January 2008) are objected to for new matter.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christina Borgeest whose telephone number is (571)272-4482. The examiner can normally be reached on 8:00am - 2:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on 571-272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christina Borgeest, Ph.D.

/Bridget E Bunner/
Primary Examiner, Art Unit 1647